Supplemental Table 9. Commonly Reported TEAEs (≥5% of Patients in Either Group) Categorized by Patient Weight Among those Receiving a 24-mcg BID Lubiprostone Dose

System Organ Class (Preferred Term, MedDRA 19.1)	Patient Weight ≥50 to ≤60 kg (n=17), No. (%)	Patient Weight >60 to <80 kg (n=8), No. (%)	Patient Weight ≥80 kg (n=6), No. (%)	Total (N=31), No. (%)
Patients with ≥1 TEAE	9 (52.9)	3 (37.5)	3 (50.0)	15 (48.4)
Gastrointestinal disorders	6 (35.3)	2 (25.0)	2 (33.3)	10 (32.3)
Diarrhea	1 (5.9)	0 (0.0)	2 (33.3)	3 (9.7)
Vomiting	2 (11.8)	1 (12.5)	0 (0.0)	3 (9.7)
Abdominal pain	1 (5.9)	1 (12.5)	0 (0.0)	2 (6.5)
Abdominal pain upper	2 (11.8)	0 (0.0)	0 (0.0)	2 (6.5)
Anal fissure	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Aphthous ulcer	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Colitis ulcerative	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Constipation	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Fecaloma	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Gastroesophageal reflux disease	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Nausea	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Immune system disorders	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Anaphylactoid reaction	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Infections and infestations	3 (17.6)	0 (0.0)	0 (0.0)	3 (9.7)
Pharyngitis streptococcal	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Sinusitis	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Viral upper respiratory tract infection	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Thermal burn	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Investigations	4 (23.5)	3 (37.5)	1 (16.7)	8 (25.8)
Blood cholesterol increased	2 (11.8)	0 (0.0)	0 (0.0)	2 (6.5)
Blood iron decreased	1 (5.9)	1 (12.5)	0 (0.0)	2 (6.5)

Alanine aminotransferase increased	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Blood phosphorus increased	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Blood thyroid stimulating hormone increased	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Blood triglycerides increased	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Glycosylated hemoglobin increased	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Heart rate irregular	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Red blood cells urine positive	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Specific gravity urine increased	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Metabolism and nutrition disorders	1 (5.9)	0 (0.0)	1 (16.7)	2 (6.5)
Decreased appetite	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Hypertriglyceridemia	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Hypokalemia	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Impaired fasting glucose	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Musculoskeletal and connective tissue disorders	1 (5.9)	0 (0.0)	1 (16.7)	2 (6.5)
Arthralgia	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Back pain	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Neck pain	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Nervous system disorders	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Headache	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Renal and urinary disorders	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Urine abnormality	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Respiratory, thoracic and mediastinal disorders	1 (5.9)	0 (0.0)	1 (16.7)	2 (6.5)
Asthma exercise induced	0 (0.0)	0 (0.0)	1 (16.7)	1 (3.2)
Cough	1 (5.9)	0 (0.0)	0 (0.0)	1 (3.2)
Skin and subcutaneous tissue disorders	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)
Rash	0 (0.0)	1 (12.5)	0 (0.0)	1 (3.2)

BID = twice daily; GI = gastrointestinal; MedDRA = Medical Dictionary for Regulatory Activities; N = total population; n = subgroup of total population; TEAE = treatment-emergent adverse event.